# PATENT COOPERATION TREATY

# PCT

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

| Applicant's or agent's file reference<br>13904PC2-PMT/SJR | **FOR FURTHER ACTION** | See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416). |
|---|---|---|
| International Application No.<br>**PCT/AU2003/001526** | International Filing Date *(day/month/year)*<br>14 November 2003 | Priority Date *(day/month/year)*<br>15 November 2002 |
| International Patent Classification (IPC) or national classification and IPC<br>**Int. Cl.** [7] A62B 9/00 18/08, A61M 16/00, B63C 11/14 11/16 | | |
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1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 3 sheets, including this cover sheet.

   [X] This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of **11** sheet(s).

3. This report contains indications relating to the following items:

   - I [X] Basis of the report
   - II [ ] Priority
   - III [ ] Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV [ ] Lack of unity of invention
   - V [X] Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI [ ] Certain documents cited
   - VII [ ] Certain defects in the international application
   - VIII [ ] Certain observations on the international application

| Date of submission of the demand<br>14 May 2004 | Date of completion of the report<br>4 February 2005 |
|---|---|
| Name and mailing address of the IPEA/AU<br>AUSTRALIAN PATENT OFFICE<br>PO BOX 200, WODEN ACT 2606, AUSTRALIA<br>E-mail address: pct@ipaustralia.gov.au<br>Facsimile No. (02) 6285 3929 | Authorized Officer<br>D. Melhuish<br>**DAVID MELHUISH**<br>Telephone No. (02) 6283 2426 |

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
**PCT/AU2003/001526**

## I. Basis of the report

1. With regard to the **elements** of the international application:*

☐ the international application as originally filed.

☒ the description, pages **1 – 3, 5 – 10, 12, 14 - 36,** as originally filed,
pages , filed with the demand,
pages **4, 11, 13,** received on **14 January 2005** with the letter of **14 January 2005**

☒ the claims, pages , as originally filed,
pages **37, 41, 42,** received on **14 January 2005** with the letter of **14 January 2005**
pages **38 – 40, 44,** received on **30 September 2004** with the letter of **30 September 2004**
pages **43,** received on **21 January 2005** with the letter of **21 January 2005**

☒ the drawings, pages **1/27 – 27/27,** as originally filed,
pages , filed with the demand,
pages , received on with the letter of

☐ the sequence listing part of the description:
pages , as originally filed
pages , filed with the demand
pages , received on with the letter of

2. With regard to the **language,** all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

4. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages

☐ the claims, Nos.

☐ the drawings, sheets/fig.

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report*

International application No.
PCT/AU2003/001526

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

| | | |
|---|---|---|
| Novelty (N) | Claims **1 – 60** | **YES** |
| | Claims | **NO** |
| Inventive step (IS) | Claims **1 - 60** | **YES** |
| | Claims | **NO** |
| Industrial applicability (IA) | Claims **1 - 60** | **YES** |
| | Claims | **NO** |

2. Citations and explanations (Rule 70.7)

Claims 1 - 60:

Claims 1 to 60 meet the requirements of PCT Articles 33(2) – (4). None of the prior art documents, or obvious combination thereof, discloses self-contained breathing apparatus comprising a source of compressed air, wherein the apparatus further comprises a medication chamber able to discharge a therapeutic agent into an air pathway of the breathing apparatus. The claims are therefore novel and inventive. The invention has industrial applicability.

pressurised or unpressurised air stream under water or on or near the surface of a body of water or elsewhere.

## SUMMARY OF THE INVENTION

Throughout this specification, unless the context requires otherwise, the word "comprise", or variations such as "comprises" or "comprising", will be understood to imply the inclusion of a stated element or integer or group of elements or integers but not the exclusion of any other element or integer or group of elements or integers. Reference to "air" includes a reference to gas or gas combinations suitable for breathing. Relevant examples include Nitrox and Heliose products.

In one aspect, the invention resides in a modified breathing apparatus for medicating an airstream, said modified breathing apparatus comprising:

a breathing apparatus comprising one of a regulator suitable for delivering air from a source of compressed air, the regulator adapted for use in scuba gear, aircraft applications, gas masks, hazardous environments, mountaineering, power assisted respirators and other similar applications, a snorkel or part thereof, a rebreathing device or a self-contained breathing apparatus;

a medication chamber adapted to store and discharge a therapeutic agent;

a delivery pathway between the chamber and an intake air pathway of the breathing apparatus; and

releasing means for selectively discharging the therapeutic agent from the chamber into the intake air pathway through the delivery pathway.

The breathing apparatus may comprise an arrangement, or part thereof, for underwater activity. The breathing apparatus may be a regulator suitable for delivery of air from a source of compressed air, either alone or in combination with another apparatus. The breathing apparatus may comprise a scuba arrangement or part thereof. The breathing apparatus may comprise a snorkel or part thereof. The breathing apparatus may comprise a gas mask, a filter mask, a respiratory mask or similar. The breathing apparatus may comprise a conduit for channelling inspiratory air. The breathing apparatus may comprise a rebreather which may be closed or semi-closed.

Alternatively, the discharge means may comprise an arrangement for dispersing a powder or liquid. The arrangement may include a rotatable blade or blades for dispensing a powder or liquid into an intake air stream.

The control means may include a flow control valve for directing air through a detour air pathway additional to the main air pathway of the snorkel.

In still a further aspect, the invention resides in a medication chamber for use in medicating an air stream in an air channelling device which may comprise one of a regulator suitable for delivering air from a source of compressed air, the regulator adapted for use in scuba gear, aircraft applications, gas masks, hazardous environments, mountaineering, power assisted respirators and other similar applications, a snorkel or part thereof, a rebreathing device or a self-contained breathing apparatus, the medication chamber comprising:

an outer housing defining an internal chamber containing a therapeutic agent;

mounting means for fixing the medication chamber to the air channelling device;

at least one delivery path from the internal chamber externally and adapted to deliver the therapeutic agent to an air pathway in the air channelling device; and

releasing means for releasing the therapeutic agent from the internal chamber.

The outer housing may be formed of one or more of plastic, polyvinyl chloride, PEEK, alloy, titanium or other suitable material. It may be formed in two interengageable sections. The two sections may be screwed threadably engaged.

The therapeutic agent may be any suitable agent including albuterol, salbutamol (Ventolin®), Beconase (Becotide®), adrenaline, aminophylline, or glucose.

The therapeutic agent may be held in a pressurised container with the release valve. The therapeutic agent may be a solid, liquid or gas.

The mounting means may comprise one or more recesses or slots for receiving a fixing device such as a screw and/or guide tab. The medication chamber may be

disassembly of the outer housing.

The outer housing may further comprise an inlet pathway for receiving a pressurised air supply. The outer housing may also comprise an outlet valve for discharging air from the internal chamber when air pressure inside the chamber exceeds pressure outside the chamber.

In yet another aspect, the invention may reside in a method of medicating an air stream in a breathing apparatus which may comprise one of a regulator suitable for delivering air from a source of compressed air, the regulator adapted for use in scuba gear, aircraft applications, gas masks, hazardous environments, mountaineering, power assisted respirators and other similar applications, a snorkel or part thereof, a rebreathing device or a self-contained breathing apparatus, the method comprising the steps of:

mounting a chamber containing a therapeutic agent to a breathing apparatus; and

introducing one or more doses of the therapeutic agent into an inlet pathway for inspiratory air.

Mounting the chamber may comprise forming the chamber integrally with the breathing apparatus or forming a separate chamber and reversibly or permanently mounting it to the breathing apparatus.

The method may include the step of positioning a container holding the therapeutic agent in the chamber. The container may be a pressurised container.

Introducing one or more doses of the therapeutic agent may include the step of activating an agent releasing mechanism such as depressing a button, rotating a control dial, knob or lever, or other voluntary action to release a dose of therapeutic agent. Introducing the therapeutic agent into an inlet pathway may comprise the step of introducing the agent directly into the inlet pathway from the chamber or, alternatively, through a delivery air pathway from the chamber to the inlet pathway.

## BRIEF DESCRIPTION OF THE DRAWINGS

CLAIMS:

1. A modified breathing apparatus for medicating an air stream, said modified breathing apparatus comprising:

a breathing apparatus comprising one of a regulator suitable for delivering air from a source of compressed air, the regulator adapted for use in scuba gear, aircraft applications, gas masks, hazardous environments, mountaineering, power assisted respirators and other similar applications, a snorkel or part thereof, a rebreathing device or a self-contained breathing apparatus;

a medication chamber adapted to store and discharge a therapeutic agent;

a delivery pathway between the chamber and an intake air pathway of the breathing apparatus; and

releasing means for selectively discharging the therapeutic agent from the chamber into the intake air pathway through the delivery pathway.

2. The modified breathing apparatus of claim 1 wherein the breathing apparatus is a second stage regulator for scuba diving.

3. The modified breathing apparatus of claim 1 wherein the breathing apparatus is a snorkel or part thereof.

4. The modified breathing apparatus of claim 1 wherein the breathing apparatus is a self-contained breathing apparatus ("SCBA") suitable for use in firefighting and rescue, industry, shipping, mining, mountaineering, hazardous environment, aircraft and/or conditions of higher or lower atmospheric pressure.

5. The modified breathing apparatus of claim 1 wherein the medication chamber is sealed to resist entry of water, mud, dust or other contaminants.

6. The modified breathing apparatus of claim 5, wherein the therapeutic agent is housed in a container, said container adapted to locate in the medication chamber.

7. The modified breathing apparatus of claim 1 wherein the medication chamber is formed integrally with the breathing apparatus.

8. The modified breathing apparatus of claim 1 wherein the medication chamber is formed for releasable engagement with the breathing apparatus.

9. The modified breathing apparatus of claim 2 further comprising balance means for substantially equalising pressure in the chamber with ambient pressure.

10. The modified breathing apparatus of claim 6 wherein the container for housing the therapeutic agent is a pressurised canister.

11. The modified breathing apparatus of claim 10 wherein the pressurised canister has a release valve which is pressure activated to discharge the therapeutic agent.

12. The modified breathing apparatus of claim 1 wherein the therapeutic agent is one or more of albuterol, salbutamol, adrenaline, beconase or glucose.

13. The modified breathing apparatus of claim 6 wherein the container comprises a capsule, a vial, a gelatine capsule or a blister pack.

14. The modified breathing apparatus of claim 1 wherein the delivery pathway is formed by the chamber being disposed along the intake airway or pathway.

15. The modified breathing apparatus of claim 1 wherein the delivery pathway is a bore, channel or aperture.

16. The modified breathing apparatus of claim 15 wherein the delivery pathway is a detour pathway adapted to direct some or all of the intake air through the chamber.

17. The modified breathing apparatus of claim 15 wherein the delivery pathway includes valve means operable to open and close the bore, channel or aperture.

18. The modified breathing apparatus of claim 17 wherein the valve means is a slide lock.

19. The modified breathing apparatus of claim 18 wherein the slide lock includes locking means to prevent unintentional activation.

20. The modified breathing apparatus of claim 19 wherein the locking means is a locking nut.

21. The modified breathing apparatus of 16 wherein the delivery pathway is formed by two or more separate pathways between the chamber and the intake air pathway.

22. The modified breathing apparatus of claim 10 wherein the releasing means comprises a rotatable dial or control for activating a displacement mechanism to displace the pressurised canister or a seat co-operating with the canister and thereby activate the release valve of the pressurised canister.

23. The modified breathing apparatus of claim 22 wherein the displacement means is a cam operated slide positioned in the medication chamber.

24. The modified breathing apparatus of claim 1 wherein a rotatable dial or control operates a mechanism to displace a measured amount of therapeutic agent and position it in the delivery pathway for discharge into the intake air pathway.

25. The modified breathing apparatus of claim 10 wherein the releasing means

includes a pressure activated button for displacing the canister or a seat cooperating with the canister to discharge the therapeutic agent through a release valve of the pressurised container.

26. The modified breathing apparatus of claim 25 wherein displacement of the seat or canister clears one or more apertures to provide or open the delivery pathway.

27. The modified breathing apparatus of any one of claims 22, 24 or 25 wherein depression of a pressure activated button or rotation of a rotatable dial or control rotates a delivery chute into a discharge position from an inactive position.

28. The modified breathing apparatus of claim 27 wherein rotation of the delivery chute clears one or more apertures to provide the delivery pathway.

29. The modified breathing apparatus of claim 1 further including counting means for indicating, at least approximately, the number of doses of therapeutic agent that have been discharged from the medication chamber.

30. The modified breathing apparatus of claim 29 wherein the counting means is formed as one or apertures in the chamber wall with moveable indicia visible therethrough, said moveable indicia providing an indication of either or both the number of dosages discharged from the chamber or the level of residual therapeutic agent in the chamber.

31. The modified breathing apparatus of claim 1 wherein a mouthpiece is formed to provide separation between the teeth of a user.

32. The modified breathing apparatus of claim 31 wherein the mouthpiece has an upper shield for receiving the upper teeth and a lower shield for receiving the lower teeth and an inlet aperture positioned between the upper and lower shields.

33. A medication chamber for use in medicating an air stream, the medication chamber comprising:

an outer housing defining an internal chamber containing a therapeutic agent;

mounting means for fixing the medication chamber to an air channelling device, said air channelling device comprising regulator adapted for use in scuba gear, aircraft applications, gas masks, hazardous environments, mountaineering, power assisted respirators and other similar applications, , a snorkel or part thereof, a rebreathing device or a self-contained breathing apparatus;

at least one delivery path from the internal chamber externally and adapted to deliver the therapeutic agent to an air pathway in the air channelling device; and

releasing means for releasing the therapeutic agent from the internal chamber.

34. The medication chamber of claim 33 wherein the outer housing is formed of metal, plastic or polyvinyl chloride.

35. The medication chamber of claim 33 wherein the internal chamber is sealed to resist entry of water, mud, dust or other contaminants.

36. The medication chamber of claim 33 wherein the outer housing is formed as two interengageable sections.

37. The medication chamber of claim 36 wherein the two sections are screw threadably engageable.

38. The medication chamber of claim 33 wherein the therapeutic agent is any one of more of salbutamol, Beconase, adrenaline, aminophylline or glucose.

39. The medication chamber of claim 33 wherein the therapeutic agent is held in a pressurised container having a release valve, the pressurisable container

locatable inside the outer housing.

40. The medication chamber of claim 33 wherein the mounting means comprises one or more recesses or slots for receiving a fixing or locating device such as a screw and/or a guide tab.

41. The medication chamber of claim 33 wherein the at least one delivery path is an outlet channel in communication with the release valve of the pressurised container.

42. The medication chamber of claim 39 wherein the releasing means includes a rotatable dial for activating a cammed mechanism to displace the canister and operate the release valve to thereby discharge a dose of therapeutic agent.

43. The medication chamber of claim 42 wherein the cammed mechanism operates a slidable seat to activate the release valve of the pressurised canister.

44. The medication chamber of claim 39 wherein the releasing means includes a pressure activated button for displacing the canister or the seat and activating the release valve.

45. The medication chamber of claim 33 wherein the releasing means comprises a mechanism for delivering a powder to the air pathway.

46. The medication chamber of claim 45 wherein the mechanism comprises a geared arrangement for advancing and opening a blister pack to present the powdered agent contained therein to the air pathway.

47. The medication chamber of claim 45 wherein the mechanism comprises a rotatable dispenser for dispensing a powdered agent to the air pathway.

48. The medication chamber of claim 45 wherein the mechanism further comprises valve means operable to open or close the delivery pathway.

49. The medication chamber of claim 33, wherein the air stream is delivered to a user's mouth or nose.

50. The medication chamber of claim 33 wherein the outer housing includes indicator means for indicating, at least approximately, the content status of the therapeutic agent in the internal chamber and/or the number of doses of therapeutic agent which have been dispensed.

51. The medication chamber of claim 33 wherein the outer housing further comprises an inlet pathway for receiving a pressurised air supply into the chamber.

52. The medication chamber of claim 51 wherein the outer housing further comprises an outlet valve for discharging air from the internal chamber when air pressure inside the chamber exceeds the pressure outside the chamber.

53. The medication chamber of claim 33 wherein the outer housing is insulated to resist thermal fluctuations.

54. A method of medicating an air stream in a breathing apparatus comprising a regulator suitable for delivering air from a source of compressed air, the regulator adapted for use in scuba gear, aircraft applications, gas masks, hazardous environments, mountaineering, power assisted respirators and other similar applications, a snorkel or part thereof, a rebreathing device or a self-contained breathing apparatus, the method comprising the steps of mounting a chamber containing a therapeutic agent to a breathing apparatus and introducing one or more doses of the therapeutic agent into an inlet pathway for inspiratory air.

55. The method of claim 54 wherein mounting the chamber may comprise forming the chamber integrally with the breathing apparatus.

56. The method of claim 54 wherein mounting the chamber includes the step of forming a separate chamber and reversibly mounting it to the breathing apparatus.

57. The method of claim 54 further including the step of positioning a container holding the therapeutic agent in the chamber.

58. The method of claim 57 wherein the container is a pressurised container.

59. The method of claim 54 wherein the step of introducing one or more doses of the therapeutic agent may include the step of activating an agent releasing mechanism by depressing a button or rotating a control dial or knob.

60. The method of claim 54 wherein the step of introducing one or more doses of the therapeutic agent into an inlet pathway may comprise the step of introducing the therapeutic agent directly into the inlet pathway from the chamber or through a delivery air pathway from the chamber to the inlet pathway.